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Clinical Audit Within the EU: Bridging the Gap Between Guidelines and Implementation

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The concept of clinical audit is not a new one, but has long been applied in some healthcare practices. The European Commission (EC) directive 97/43/EURATOM (MED) introduced this concept for the assessment of medical radiological practices. The MED-directive defined clinical audit as:

"A systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review, whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modifications of the practices where indicated and the application of new standards if necessary".

It is clear from this definition, that clinical audit ought to be a multidisciplinary activity.

EU Member States are required to implement clinical audits “in accordance with national procedures” (Article 6.4 of the MED). By now there has been high variation between the approaches of the Member States in its implementation and therefore, further guidance has been deemed necessary.

In 2007 - 2008, the EC conducted a special project to review the current status of implementing clinical audit in the Member States and to provide guidance on clinical auditing for an improved implementation of Article 6.4 of the MED. The project consortium was led by the Radiation and Nuclear Safety Authority (STUK), Helsinki, Finland, and other partners together with a scientific panel of experts representing hospitals, European or national professional societies, authorities and auditing experts from ten European countries. Before submission to the EC, the draft guideline was subjected to critical reviews by major scientific professional organisations and further introduced and discussed in an international workshop.

Status of Audit Implementation in Europe

The status of the implementation of clinical audit was reviewed by a questionnaire sent to the Member States, including some candidate and associated states. About 80% of them replied. The results confirmed the earlier findings about the diversity of approaches to clinical auditing and the lack of practical implementation in several Member States.

While in some countries a systematic approach to clinical audit had been established (e.g. in the UK, Germany, France and Finland), in most countries clinical audits were only occasional or had not been implemented in practice. Several problems were identified: incomplete national legislation, poor understanding of the purpose of clinical audits, lack of formal framework of auditing, lack of criteria for standards of good practice and practical problems of implementation such as financing of audit work. In some countries, clinical audit seemed to be confused with internal quality assurance programmes or external assessments such as accreditation and regulatory inspections.

EC Guideline on Clinical Audit

The EC guideline provides a general framework for the Member States in order to establish sustainable national systems of clinical auditing of radiological practices (e.g. diagnostic radiology, nuclear medicine and radiotherapy). It is sufficiently flexible and will enable Member States to adopt a model of clinical audit with respect to their national legislation and administrative provisions.

The guidance introduces the basic principles of clinical audit (objectives, coverage, standards of good practice, etc.) aimed at clarifying its profound meaning and recommended application. It defines the topics that should be covered while the criteria of good practice are discussed only on generic levels. It discusses the interrelation of clinical audit with other audit systems such as certification of quality systems, accreditation, peer review and quality award, and also its interrelation with regulatory control. Finally, it gives general advice for the practical implementation of audits, including organisation of audits, recommendations for auditors, models of financing, national coordination and the role of scientific and/or professional societies and regulatory authorities.

It is important to recognise that the EC guideline is not an obligatory, or legal requirement. It will only give recommendations and highlight some possible “national procedures” as expected by the MED. However, the general framework that is published in the EC guideline is well supported by other international and national developments, e.g. the practical guides published by the International Atomic Energy Agency (IAEA) or the AuditLive system in the UK.

Essentials of Clinical Audit

The general purpose of any clinical audit is to:

• Improve the quality of patients’ care;

• Improve the effective use of resources;

• Enhance the provision and organisation of clinical services, and

• Further professional education and training.

Clinical audit should thus address the structure, process and outcome of practices. For diagnostic radiological procedures, the priorities should be as shown in Table 1 *(see above)*. Clinical audit should be a continuous activity for quality improvement.

Both internal audits (where auditors come from inside a given healthcare unit) and external audits (where auditors come from outside the unit) should be implemented. These are of equal importance and should supplement each other. External audits are needed to remove possible “blindness” of internal experts to recognise weaknesses in their own unit and to give more universal and broader perspectives.

These standards of good practice should be derived from evidence-based data, long-term experience and knowledge gained. In practice, these can be adopted from legal requirements, results of research, consensus statements, recommendations by learned societies, or local agreements (if there is no other more universal reference).

Clinical audit should not be confused with:

• Research;

• Quality (system) audit to verify that the quality systems conform to a quality standard;

• Accreditation, or

• Regulatory inspection, nor any other regulatory activity.

Conversely, clinical audits should be developed to supplement, and not duplicate, other efforts of quality assessments. The practical organising of external clinical audits can be through site visits of an audit team or, for a limited part of practices with relevant documented or measurable data, by mailed review and central analysis of the data.

Impact and Future

Clinical audit is an important tool of quality improvement in medical imaging, and can have a major impact on developing practices in compliance with the most recent data on good imaging practices. Audits will yield multiple benefits to the healthcare system, such as:

• Improvement of practice;

• Recognition for quality and awareness of good practices;

• Recognition of outdated practices;

• Motivation of staff to increase quality;

• Improvement of local standards and adherence to national standards;

• Prevention against litigation;

• Improvement of communication within the institution;

• Revealing weak points, and

• Promoting development of quality systems.

Future work for the promotion of clinical audits should aim to collect and report the beneficial experiences gained from various levels and approaches to clinical audit.

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